

**DOCKET NO. HARR0018-100**  
**Application Serial No. 09/889,761**  
**Request For Reconsideration Dated July 22, 2004**  
**Reply To Office Action Of March 23, 2004**

**PATENT**

### **REMARKS**

Claims 1-21 were pending and subject to restriction. In the Office Action, the restriction requirement was made final. Claims 18-21 have been withdrawn from consideration as directed to a non-elected invention. Claims 1-17 of Group I were examined as regards the elected species of an enzyme capable of converting a prodrug to its active form, more specifically, nitroreductase.

The Office Action further indicates, however, that antibiotic resistance was selected as the selectable marker and CB 1954 as the prodrug. Applicant, however, does not recall making these additional species elections, nor is there any record thereof. Applicant was, rather, under the impression that the confusion over whether one species from **each** of categories (a) through (e), or just a single species from **one** of the categories, had to be chosen had been clarified with the prior examiner to mean that a single species from one of the categories had to be chosen. Applicant requests further clarification in view of the Office's recitation of additional species selected.

Preliminarily, the abstract of the disclosure was objected to because of the use of the word "comprises," which the Office asserts is often used in patent claims. The Office, thus, required correction thereof. MPEP § 608.01(b) is cited in support. MPEP § 608.01(b), however, cites the use of language such as "means" and "said." Such terms are unique to claims, which is not the case with the word "comprises." Regardless, MPEP § 608.01(b) simply

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says that the use of such language "should" be avoided, not that it must be. Applicant's position is that such correction is unnecessary but will do so if this objection is maintained.

**Rejection Under 35 U.S.C. § 112, first paragraph**

Claims 1-17 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the Written Description Requirement. The Office alleged that the specification does not provide an adequate description for a method that uses **any type** of prodrug, enzyme that cleaves the prodrug, and bacteriophage library. Applicant respectfully traverses this rejection.

The Office is directed to the recitation in the claims regarding the prodrug activating the proteolytic activity of bacterial RecA. The method, thus, does not use any type of prodrug as the Office alleges but, rather, prodrugs that activate the proteolytic activity of bacterial RecA.

The citation to Fischetti et al. seems misplaced. The cited passage of Fischetti et al., i.e., column 2, lines 1-14, is not directed to phage libraries but, rather, the use of bacteriophage to treat bacterial infections.

Applicant requests that this rejection be withdrawn.

**Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 5 and 10 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

The Office rejected the recitation of “other selectable marker” in claim 5 as indefinite because it is allegedly “indefinite as to what is included or excluded by the term “other.” Applicant respectfully submits that the reference to “other selectable marker” in claim 5 is clearly in relation to antibiotic resistance and, therefore, means a selectable marker other than antibiotic resistance.

The Office also alleged that claim 10 is indefinite in view of the phrase “and/or.” That claim 10 uses “and/or” language does not render it indefinite. Applicant respectfully submits that the metes and bounds of the claim are clear and that such a claim is no different from one reciting that the variants “comprise insertions, deletions, or substitutions, of the wild type enzyme, or combinations thereof.”

Applicant respectfully requests that this rejection be withdrawn.

**Rejection Under 35 U.S.C. § 102(e)**

Claims 1-5 and 8-15 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by the patent **publication** -- Maruyama et al. Applicant respectfully traverses this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Office seems to be completely overlooking several elements of Applicant’s claims that are not disclosed or suggested in Maruyama et al. such as, 1) the screening of a

population of **bacteria** transformed with a bacteriophage library and 2) that the activated prodrug activates RecA in the bacteria.

Maruyama et al., rather, involves phage display selection methods, i.e., screening a population of phage (see, for example, ¶¶ 0245, 0250, and 0356 of Maruyama et al., as well as the examples on page 28 through 35, and claims 22-24), or screening the fusion proteins of the invention bound to carriers (see, for example, ¶ 0362 of Maruyama et al.). Since Maruyama et al. does not disclose or suggest the use of bacteria in the screening, the claimed proteolytic activity of the bacteria cannot be a property inherently contained in the bacteria of Maruyama et al.

The missing elements are recited in independent claims 1 and 2. All remaining claims ultimately depend from claims 1 and/or 2. Accordingly, Maruyama et al. is not an appropriate reference under 35 U.S.C. § 102(e) against any of claims 1-5 or 8-15. Applicant respectfully requests that this rejection be withdrawn.

#### **Rejection Under 35 U.S.C. § 103(a)**

Claims 1-17 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over McNeish in view of Maruyama et al. or Murray. Both McNeish and Murray were cited in Applicant's Information Disclosure Statement. Applicant respectfully traverses this rejection.

As discussed above, discussion incorporated herein, Maruyama et al. does **not** disclose or suggest several of Applicant's claim limitations – i.e., 1) screening of a population of bacteria

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transformed with a bacteriophage library or 2) that the activated prodrug activates RecA in the bacteria. Neither McNeish nor Murray overcomes these deficiencies. McNeish reports on treatment of ovarian and pancreatic cancer using nitroreductase, and the generation of pooled populations of non-bacterial cell lines. Murray reports on the construction and screening of phage libraries; it does not disclose or suggest the screening from phage-transformed bacteria as presently claimed.


Applicant respectfully requests that this rejection be withdrawn.

### **CONCLUSION**

For the foregoing reasons, Applicant respectfully submits that all claims are allowable and requests early notification of the same. If the Office disagrees, the Examiner is requested to call the undersigned at 215-665-5593 to discuss.

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Respectfully submitted,

  
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